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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,904	11/30/2001	Harold R. Garner	119929-1037	4132
34725	7590	10/19/2005	EXAMINER	
CHALKER FLORES, LLP 12700 PARK CENTRAL, STE. 455 DALLAS, TX 75251			MORAN, MARJORIE A	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/998,904

Applicant(s)

GARNER ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/22/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-7,9-42,44-53 and 56-213 is/are pending in the application.
- 4a) Of the above claim(s) 11,13-21,23-36,58-202 and 205-213 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7,9,10,12,22,37-42,44-53,56,57,203 and 204 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/7/03 has been entered.

Election/Restrictions

Claims 11, 13-21, 23-36, and 58-202, and 205-213 are again withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in a paper filed 11/3/03..

An action on the merits of elected claims 1-3, 5-7, 9-10, 12, 22, and 37-42, 44-53, 56-57, 203 and 204, as they read on the elected species, follows.

All rejections and objections not reiterated below are hereby withdrawn.

Claim Rejections - 35 USC § 112

Claims 1-3, 5-7, 9-10, 12, 22, and 37-42, 44-53, 56-57, 203 and 204 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the

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specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a LACK OF ENABLEMENT rejection.

The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

The claims are not enabled because neither the prior art nor specification teaches how to identify the locations of single nucleotide polymorphisms that will likely cause a variation in one or more bases of a nucleic acid sequence.

It is noted that a single nucleotide polymorphism (SNP), by definition, IS a variation in a single base, therefore it would be redundant or impossible, depending on one's interpretation of the claims, to identify a SNP that "likely" causes a variation in a base of a nucleic acid sequence. Where the method is interpreted as predicting a SNP, then it is inherently a method of predicting the variation of one or more bases in a nucleic acid sequence, and the final "step" is redundant. If the method is actually intended to be one of identifying SNPs that cause variations (SNPs that cause SNPs? SNPs that cause other mutations?), then the method is not enabled as one skilled in the art would not know how to predict a SNP or other single nucleotide variation "caused by" a location of a SNP. Neither the prior art nor the instant specification teach how to predict a base variation "caused by" a SNP or knowledge of a SNPs location. If the method is intended to be one of predicting the likelihood of a SNP occurring at any

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given (or selected) position in a nucleic acid sequence, then it is noted that the claims do not actually recite this limitation.

Further with regard to the previous enablement rejection, applicant's arguments filed 6/7/05 have been fully considered but they are not persuasive.

Applicant argues that the specification teaches how to obtain a variation or *codon* predictiveness matrix. As the claims now recite specific steps for generating a predictiveness matrix for *codons*, the arguments with regard to generating such a matrix are persuasive for claim 45-46 and 204. It is noted that the specification teaches only comparison of codons to identify areas of a nucleic acid sequence which may contain SNPs. The specification does not teach a predictiveness matrix based on comparison of individual nucleic acids between sequences in a database, nor comparing *individual bases* from a sequence with a variation predictiveness matrix based on *codon changes* from a database of sequences, to identify SNPs, therefore the argument that one skilled in the art could predict location of SNPs using the claimed steps is not persuasive for claims 1-3, 5-7, 9-10, 12, 22, 37-42, 44, 47-53, 56-57, and 203. Further, applicant argues on page 28 of the response that the specification teaches how to provide a relative ranking of SNPs within a subject sequence; i.e. whether one codon is more or less "likely" to comprise a SNP relative to other codons in a gene. This limitation is not reflected in the claims.

For these reasons, those previously set forth and set forth above, the examiner maintains that the claims are not enabled.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon,Wed: 7-1:30; Tue,Thur: 7:30-6; Fri 7-3:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
10/17/05